DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 May 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The language “wherein one of the receptacles fits completely inside of the other of the receptacles”. This language is not found in the original specification and cannot be supported by the drawings. The drawings appear to support (see Fig. 12) the inner receptacle fitting within the outer receptacle so at most

the bottom side of the inner receptacle is flush with the bottom side of the outer receptacle, but not completely inside.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 1-8, 17, 18, 21, 23, and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (US 5,236,460) in view of Kuntz (US 4,349,921).

a. Claim 1 and 18: Barber teaches an implant that can be used in procedures for stiffening the vertebral column, the implant comprising an enclosed hollow body 11 which includes at least a movable open interior receptacle 23 and a movable open exterior receptacle 13, oriented toward one another and interlock (Figure 3, the two parts fit together), and are movable from a first position (Fig. 2) to a second spread apart position (Fig. 3) by inserting a filling material (Column 3, Lines 18 and 19). The implant is bean shaped (seen in Figs. 1, 5, and 6) and has a front end and rear end. The rear end includes a connection 17 for attaching an implantation instrument 55 and is adapted for connection to a device (59 and 61) used to generate a filling pressure. One of the receptacles fits within (embodied by 23 fitting into 13; within. (n.d.). *Dictionary.com Unabridged (v 1.1)*. Retrieved February 19, 2008, from Dictionary.com website:

http://dictionary.reference.com/browse/within) the other of the receptacles when the receptacles are in the first position (Fig. 2).

Barber does not though specifically teach having the wedged shaped front end and includes top and bottom inclined wedge surfaces, and extends to a full height of the implant. Kuntz, however, suggests a wedge shaped front end 16 that includes top and bottom inclined wedge surfaces, and extends to a full height of the implant to allow the implant to be tapped in, therefore separate distraction of the vertebrae is not needed. Additionally, Kuntz suggests grooves 13 that allow an implant to slide into the vertebral space and to hold the implant in the vertebral space once inserted (see col. 6, l. 28-38). It would have been obvious to someone of ordinary skill in the art at the time the invention was made to **add** the wedge shaped insertion end of Kuntz and to substitute the spikes for the grooves of Kuntz in the invention of Barber in allow the implant to be tapped in, therefore distraction of the vertebrae is not needed, without loosing the function of holding the implant in the vertebrae after insertion. The substitution of one know anchoring means, grooves, for another, spikes would have been obvious because it would have yielded predictable results, namely to hold the implant in the vertebral space after insertion. The grooves would allow the modified implant to be slid into the vertebral space.

b. Claim 2-8, 17, 21, and 23: Barber discloses two receptacles which interlock (Figure 3, the two parts fit together); the implant can be connected to a supply hose (embodied by Figure 5 and 6, 55 is referred to as a injecting tool in

Column 3, Line 5 and can be see as a flexible tube); the other end of the supply hose is adapted for connection to said device (59 and 61) used to generate a filling pressure; the implant has an opening 17, for connecting the supply hose, which is also used for attaching an instrument (55 is also used as an installation tool, Column 6, Line 66 and Column 3, Lines 11-13) used to insert the hollow body; the filling material is made of a tissue compatible, liquid (Column 3, Lines 52-54) or initially liquid phase, self-hardening material (Column 3, Lines 1-21); the hollow body is structured on one part or over an entire surface thereof (grooves 13 of Kuntz); the receptacles are sealed (Column 2, Lines 24-25) with one another; the hollow body is compressed to minimum height before implantation (Figure 2) and said device is attached (59 and 61 through 55) to the hollow body to expand the hollow body after implantation (Column 3, Lines 18-19); the receptacles are pressurized and have a form of a partial cylinder 23 and 13, whereby base and cover plates (19 and 29) are included that are slightly arched (embodied by arches of the outer edge of 19 and 20) and are positioned parallel relative to each other (Fig. 3, 19 and 29).

c. Concerning 19 and 20: Barber in view of Kuntz suggests the claimed invention above except for the implant being manufactured from a metal, polymer or a composite material or using a material that would produce radiological shadows. However, metals, polymers, composite materials and materials that would produce radiological shadows are art recognized materials for implants. It would have been obvious to one having ordinary skill in the art at the time the

invention was made to form the implant of a metal, polymer or a composite material or using a material that would produce radiological shadows, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

4. Claims 9, 10, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) in view of Kuntz (US 4,349,921) as applied to claim 1 above, and further in view of Strnad et al. (U.S. Patent 6,296,665) and Biedermann et al. (U.S. Patent 5,989,290).

d. Barber, in view of Kuntz, fairly suggests the claimed invention including the receptacles being adjustable to each other, but does not teach whereby the adjusting movement is limited to a certain area, which ensures a mutual overlapping of the receptacles (claim 9 of the instant application) and that this area is limited though a screw in one of the two receptacles catching in a slit in the other of the two receptacles (claim 10 of the instant application).

Strnad et al. teaches a pin 118 carried by the upper portion 102 that is disposed in a slot 120 of the lower portion 106 for the purpose of preventing the upper and lower portions from becoming disconnected (col. 5, ll. 29-35), and thus the adjusting movement of the upper and lower portions is limited to a certain area that ensures a mutual overlapping of the portions. It would have been obvious to someone of ordinary skill in the art at the time the invention was made to provide a pin to the lower body 13 of the modified invention of Barber, in view

of Kuntz and Strnad et al., in order to prevent the upper and lower portions from becoming disconnected, and thus limiting the adjusting movement and ensuring a mutual overlapping of the receptacles.

Biedermann et al. suggests using a tightening screw 11 to allow two open receptacles of an implant to be locked in relation to each other. It would have been obvious to someone of ordinary skill in the art at the time of the invention to substitute the pin of Strnad et al. for the tightening screw of Biedermann in the modified invention of Barber, in view of Kuntz and Strnad et al., in order to allow the receptacles to be locked in relation to each other. It further would have been obvious to have the screw attached at the rear end so that the screw could be manipulated after the implant was inserted.

Note: The following rejection of claim 1 is based on the selection of the second choice of the alternative limitation of "inserting a filling material or **utilizing a filling material made of an elastomer**" (emphasis added). "Inserting a filling material" is taught by Barber.

5. Claims 1 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) in view of Kuntz (US 4,349,921) as applied to claim 1 above, and further in view of Ferree (U.S. Patent 6,419,704).

e. Claim 1 and 11: Barber, in view of Kuntz, fairly suggest the claimed invention including a resin or other liquid as a filling material, but not specifically a filler being made of an elastomer (Claim 11). Ferree teaches that an implant can be filled with an elastomer, amongst other materials (Column 5, Lines 42-45),

which will enable the implant to cyclically compress and expand in a manner similar to the disc material being replaced (refer to Abstract). It would have been obvious to someone of ordinary skill in the art at the time the invention was made to use an elastomer as the filling material in the modified invention of Barber, in view of Kuntz and Ferree, in order to enable the implant to cyclically compress and expand in a manner similar to the disc material being replaced.

f. Claim 12, 13, and 14: the elastomer would at least partially fill the space (Fig. 3); the elastomer would have been fitted to an inner side wall of the hollow body (Fig. 3); the upper and bottom walls are generally planar and would have contacted the elastomer when compressed (Fig. 3).

6. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) in view of Kuntz (US 4,349,921) and Ferree (U.S. Patent 6,419,704) as applied to claim 1 above, and further in view of Powell (U.S. Patent 4,517,844).

g. Claim 15 and 16: Barber, in view of Kuntz and Ferree, fairly suggests the claimed invention including the desirability of the implant to cyclically compress and expand in a manner similar to the disc material being replaced and that air can be used as a filling material (col. 5, ll. 40-43), but do not suggest an air bubble or space added to the elastomer. Powell teaches that elasticity can be changed by air bubbles to a system. It would have been obvious to someone of ordinary skill in the art at the time the invention was made to add an air bubble to the filling material of the modified invention of Barber, in view of Kuntz, Ferree,

and Powell, in order to change the elasticity to allow for the implant to better compress and expand in a manner similar to the disc material being replaced. Concerning claim 15, a space below the elastomer would be functionally equivalent to an air pocket, or air bubble, and thus would change the elasticity to allow for the implant to compress and expand in a manner similar to the disc material being replaced.

Response to Arguments

4. Applicant's arguments with respect to claim 1-21 and 24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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